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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,865	10/15/2001	J Kevin Donahue	56495-2 (71699)	3724

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

9
DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,865

Applicant(s)

DONAHUE ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27,36-38,48-50,57-59,61, 63,64,66 and 70-96 is/are pending in the application.
- 4a) Of the above claim(s) 27,36-38,48-50,57-59,63,64 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 70-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 27, 36-38, 48-50, 57-59, 61, 63, 64, 66 and new claims 70-96 are pending in the present application. This restriction is in the election of Paper No. 8, filed 7 July 2003 in which Applicant elected Group I, claim 1 and added new claims 70-96. This Supplemental Restriction relates to elected Group I which includes claim 1 and new claims 70-96. Claims 27, 36-38, 48-50, 57-59, 63, 64 and 66 have been withdrawn from consideration.

Supplemental Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: A method for administering a nucleic acid to a cell comprising administering a phosphodiester inhibitor compound. The species comprising phosphodiester inhibitor compounds include:

- (a) pyrazolo[4,3-d]pyrimidin-7-one;
- (b) pyrazolo[3,4-d]pyrimidin-4-one;
- (c) quinazolin-4-one;
- (d) purin-6-one; and
- (e) pyrido[3,2-d]pyrimidin-4-one.

These species are patentably distinct and so diverse in chemical structure that a reference anticipating one of the species would not anticipate or render obvious to other species. Thus, the stated species are capable of supporting separate patents. The divergence among these species can be demonstrated by their different classification. For example: pyrazolo[4,3-d]pyrimidin-7-

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one is classified in class 514, subclass 262; and pyrazolo[3,4-d]pyrimidin-4-one is classified in class 514, subclass 253. As are the other compounds listed.

Moreover, claim 75 recites a plurality of disclosed species comprising a second permeability agent. The species comprising the second permeability agent are as follows:

- (a) serotonin;
- (b) bradykinin;
- (c) platelet-activating factor;
- (d) prostaglandin E₁;
- (e) histamine;
- (f) vascular endothelium growth factor;
- (g) zono occludens toxin;
- (h) interleukin-2;
- (i) plasma kinins;
- (j) L-N-monomethyl arginine; and
- (k) L-N-nitro-arginine methyl ester.

These claims encompass species that are so diverse in chemical structure that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus, the stated species are capable of supporting separate patents. The divergence among these species can be demonstrated by their different classification. Moreover, the claims encompass many difference possibilities and combinations of PDE inhibitors with each of the above listed actives. Therefore, as demonstrated the diversity of species in the claims requires a search of many different subclasses, which constitutes an serious burden on the Office. Note that searches

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are not limited to patent files. Applicant is required under 35 U.S.C. 121 to elect a single species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 70, 71, 73, 74 and 76-96 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
August 19, 2003


JAMES KETTER
PRIMARY EXAMINER